## REMARKS/ARGUMENTS

In this Amendment, claims 30-34, 36-45 and 47-64 remain as previously presented and claims 1-29, 35 and 46 remain canceled without prejudice or disclaimer. Accordingly, the currently pending claims are claims 30-34, 36-45 and 47-64.

## Double Patenting

Claims 30-32, 34, 47 and 52-61 were provisionally rejected under 35 U.S.C. §101 as allegedly claiming the same invention as that of claims 29-34, 36-41, 46 and 47 of co-pending application U.S. Serial No. 10/461,393 (hereinafter "the '393 application"). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

In the Advisory Action dated June 6, 2005, the Examiner states that "[a]pplicants argue that the difference between the two sets of claims is that in the co-pending '393 application the molecular weight of the amylopectin is specifically reduced by acid hydrolysis whereas in the starch of the instant claims the molecular weight of the amylopectin is reduced by shearing. A comparison of the starches of the instant and the copending claims shows that the characteristics like molecular weight ranges, purity levels and dissolution characteristics in water are identical." The Examiner concludes that "[t]he mode of molecular weight reduction is not seen to render the starch claimed in either application patentably distinct" and that the submitted declaration of Dr. Jones "is an opinion that is not seen to overcome the statutory 101 double patenting rejection".

It is respectfully submitted that claims 30-32, 34, 47 and 52-61 of the instant application are drawn to a pharmaceutically acceptable starch that is **not** the same as that described in claims 29-34, 36-41, 46 and 47 of the '393 application. In the instant case, the claims are directed to a pharmaceutically acceptable starch and microparticles based on this starch, in which the starch has undergone molecular weight reduction by shearing. Claims 29-34, 36-41, 46 and 47 of the co-pending '393 application are directed to a starch in which the molecular weight of amylopectin is specifically reduced by acid hydrolysis. The claims of the two applications reflect that a different process, i.e., shearing or acid hydrolysis, is used to reduce the molecular

weight of amylopectin so that at least 80 percent by weight of the starch lies within the described molecular weight range. As demonstrated by the accompanying second declaration of Dr. Richard E. Jones under 37 C.F.R. §1.132 (referred to herein as " the Jones Declaration"), starch that is produced by shearing is not the same as starch that is produced by acid hydrolysis.

In light of the current Jones Declaration and as would be understood by the skilled practitioner in this art, the presently claimed invention, in which shearing is used to reduce the molecular weight of amylopectin, yields a starch product that is discernibly different from that produced by acid hydrolysis. It is respectfully submitted that the use of acid hydrolysis versus shearing to reduce the molecular weight of the resulting starch product is to be given consideration as recited in the claims. A consideration of all of the claim limitations as recited in the claims shows that the claims in the instant application and those in co-pending '393 application are not identical.

To further support the teachings of the specification in connection with the differences and distinctions between a starch product in which the molecular weight of amylopectin is reduced by shearing versus a starch product in which the molecular weight of amylopectin is reduced by acid hydrolysis, the accompanying Jones Declaration presents and describes the results of experiments that unequivocally demonstrate the differences between a starch whose molecular weight is reduced by shearing and a starch whose molecular weight is reduced by acid hydrolysis.

In the Jones Declaration provided herewith, the experimental results evidence the differences between a sheared starch versus an acid hydrolyzed starch. It can be observed that acid hydrolyzed starch comprises a generally lower molecular weight species than does the sheared starch, as well as a broader molecular weight distribution. (*See*, the accompanying Jones Declaration at ¶¶6 and 7 and Tab 1). Moreover, acid hydrolyzed starch displays a much broader molecular weight distribution compared with sheared starch, as well as a generally lower molecular weight. (*See*, the accompanying Jones Declaration at ¶¶6 and 7 and Tab 2).

As described in the instant application and as pointed out and evidenced by the accompanying Jones Declaration, the starch product claimed in the instant application and the

starch product claimed in the '393 application are considered to be distinct and non-overlapping products, as the use of shearing to reduce the molecular weight of amylopectin comprising the starch (as described in the instant application) results in a more narrow molecular weight distribution of the resulting starch fragments compared with acid hydrolysis. In addition, within the claimed parameters, acid hydrolyzed starch displays generally lower molecular weight species compared with sheared starch.

Thus, it is respectfully submitted that the claims of the instant application and those of the '393 application are not identical, as they are drawn to different starch products by virtue of the recited processes used to reduce the molecular weight of the amylopectin starch component.

In consideration of the above discussion and the evidence presented in the accompanying Jones Declaration, Applicants submit that the present claims are not directed to the same invention as the relevant claims of the '393 application. Accordingly, withdrawal of the 35 U.S.C. §101 rejection is respectfully requested.

## CONCLUSION

Applicants respectfully submit that the present application is now in condition for allowance. An action progressing this application to issue is courteously urged.

Should any additional fees be deemed to be properly assessable in this application for the timely consideration of this Amendment, or during the pendancy of this application, the Commissioner is hereby authorized to charge any such additional fee(s), or to credit any overpayment, to Deposit Account No. **50-0311**; Reference No. **28069-585-DIV**; Customer No. **35437**. Should an extension of time further to that requested herein be required in this application, the Commissioner is hereby requested to grant a petition for an extension of time such as may be required, and to change any fee(s) related thereto, to the aforementioned Deposit Account No., Reference No. and Customer No.

If the Examiner believes that further discussion of the application would be helpful, he is respectfully requested to telephone the Applicants' undersigned representative at (212) 692-6742 and is assured of full cooperation in an effort to advance the prosecution of the instant application and claims to allowance.

Respectfully submitted,

MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C.

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By: Leslie A. Serunian
Leslie A. Serunian
Registration No. 35,353

Correspondence Address:
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY
AND POPEO, P.C.
Chrysler Center
666 Third Avenue
New York, New York 10017
Telephone: (212) 935-3000
Facsimile: (212) 983-3115
Direct Tel.: (212) 692-6742